

DISCOVERY OmniMap anti-Rb HRP

REF 760-4311
05269679001
Σ 125

DISCOVERY OmniMap anti-Ms HRP

REF 760-4310
05269652001
Σ 125

DISCOVERY OmniMap anti-Rt HRP

REF 760-4457
05891892001
Σ 125

DISCOVERY OmniMap anti-Gt HRP

REF 760-4647
06607233001
Σ 50

INTENDED USE

For Research Use Only. Not for use in diagnostic procedures.

SUMMARY AND EXPLANATION

Since its invention in the 1940s, immunohistochemistry (IHC) has become a routine and essential tool for many laboratories across many applications. Automation of IHC in the late 20th century increased the power of this tool for demonstrating the presence of unique antigens in tissue and cells.

One of the most routine IHC methods is the use of streptavidin conjugates to target the antigen of interest. Streptavidin-horseradish peroxidase conjugate is used to catalyze the 3,3'-Diaminobenzidine tetrahydrochloride (DAB) / H₂O₂ reaction to produce an insoluble dark brown precipitate that can be visualized.

OmniMap anti-Rb HRP, OmniMap anti-Ms HRP, OmniMap anti-Rt HRP, and OmniMap anti-Gt HRP are biotin-free conjugates based on proprietary multimer technology. They consist of a robust chemistry that provides clean background in combination with enhanced specificity and sensitivity, which increases the signal-to-noise ratio. They are designed to be used in conjunction with the DISCOVERY series of instruments and Ventana Medical Systems' ancillary reagents for optimal performance.

MATERIAL PROVIDED

For flexibility, the detection systems are split between the specific conjugate, OmniMap HRP conjugate and the universal DAB chromogenic kit, ChromoMap DAB. Therefore, the same chromogenic kit can be used with two or more conjugates on the same instrument run. Conjugate and ChromoMap DAB can be ordered together or individually; however, both are required to obtain IHC results. Refer to the Kit Components table for further information.

Description	Components	Test Size
OmniMap HRP conjugate	OmniMap anti-Rb HRP	125
	OmniMap anti-Ms HRP	125
	OmniMap anti-Rt HRP	125
	OmniMap anti-Gt HRP	50

MATERIALS REQUIRED BUT NOT PROVIDED

Both the Conjugate and the ChromoMap DAB are required to obtain IHC results. The components can be ordered together or individually. Below is a list of the related components that need to be run with the specific conjugates to obtain IHC results.

Description	Components	Test Size
ChromoMap DAB Kit	Inhibitor CM* (For reducing the endogenous peroxidase activity)	125
	DAB CM* (Diaminobenzidine in stabilizer solution with preservative)	125
	DAB H ₂ O ₂ CM* (Substrate for peroxidase)	125
	Copper CM* (Copper sulfate solution)	125

* CM indicates ChromoMap

STORAGE AND STABILITY

Upon receipt and when not in use, store at 2-8°C. Do not freeze.

WARNINGS AND PRECAUTIONS

1. For Research Use Only (RUO).
2. For professional use only.
3. Do not use beyond the specified number of tests.
4. ProClin 300 solution is used as a preservative in this reagent. It is classified as an irritant and may cause sensitization through skin contact. Take reasonable precautions when handling. Avoid contact of reagents with eyes, skin, and mucous membranes. Use protective clothing and gloves.
5. Positively charged slides may be susceptible to environmental stresses resulting in inappropriate staining. Ask your Roche representative for more information on how to use these types of slides.
6. Materials of human or animal origin should be handled as biohazardous materials and disposed of with proper precautions. In the event of exposure, the health directives of the responsible authorities should be followed.^{1,2}
7. Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
8. Avoid microbial contamination of reagents as it may cause incorrect results.
9. For further information on the use of this device, refer to the instrument User Guide, and instructions for use of all necessary components located at navifyportal.roche.com.

- Consult local and/or state authorities with regard to the recommended method of disposal.
- Product safety labeling primarily follows EU GHS guidance. Safety data sheet available for professional user on request.
- To report suspected serious incidents related to this device, contact the local Roche representative and the competent authority of the Member State or Country in which the user is established.

This product contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

Table 1. Hazard information.

Hazard	Code	Statement
	H317	May cause an allergic skin reaction.
	P261	Avoid breathing mist or vapours.
	P272	Contaminated work clothing should not be allowed out of the workplace.
	P280	Wear protective gloves.
	P333 + P313	If skin irritation or rash occurs: Get medical advice/ attention.
	P362 + P364	Take off contaminated clothing and wash it before reuse.
	P501	Dispose of contents/ container to an approved waste disposal plant.

This product contains CAS #s:

- 55965-84-9, a reaction mass of: 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)
- 2682-20-4: 2-methyl-2H-isothiazol-3-one

INSTRUCTIONS FOR USE

Register the kits on your DISCOVERY series instrument, as described in the on-screen directions. Open the package, and take out the dispensers. Remove the cap from the nozzle of each dispenser, and place it on the nozzle cap holder on the rear of the dispenser. While holding the dispenser upright, remove the yellow shipping key by pulling the key tab to disengage it from each end. Do not cover the nozzle tip or depress the dispenser while removing key. Place the dispensers on the reagent tray, along with the appropriate accessory reagents.

The DISCOVERY series of instruments with any of the OmniMap HRP Conjugates and the ChromoMap DAB Kits form an integrated system. ALL KIT COMPONENTS MUST BE USED TOGETHER in order to obtain high-quality and consistent results. Omitting or changing any of the solutions may compromise the final outcome.

Bulk reagents should be prepared using quality reagent-grade water, not tap water. Carboys for storing bulk reagents should be rinsed thoroughly between fillings.

CONTROLS

DAB staining results can be affected by endogenous peroxidase activity. Therefore, it is important to include a negative control on every tissue tested to identify areas of endogenous peroxidase activity and/or nonspecific binding of antibody. When this is done, the specificity of the staining reaction can be documented by comparing the negative control staining to the primary antibody staining. In addition, a known positive tissue should be run with every assay. The staining of the positive control serves as a baseline for evaluating run-to-run and/or day-to-day consistency.

SAVING THE PROTOCOL

- After all options have been selected (i.e., no more yellow boxes), click on the "Save As" button. Fields will appear for a protocol name and protocol number. Type in an unused name for the protocol, and select an unused number in the appropriate boxes. Click on the "Save" button, and the protocol will be saved.

PREPARING LABELS AND LOADING SLIDES

- From the toolbar on the bottom of the main screen, click on the bar code symbol. Click on the "Protocols" button. Highlight the protocol number and name desired in

the protocol field. Click on the "Add>>" button once for each protocol bar code label you want to print. Click on the "Close/Print" button. Enter any additional information you want to appear on the label in the "User Prompt" fields. Click the "Print" button. When the last bar code has been printed, click on the "Exit" button.

- Place the bar code(s) on the slide(s), load them carefully onto the instrument, close the instrument, and click on the "Run" button. Click on the "Reagents/Reagent Tray Loaded" box and "Reagent Caps Removed" box. Enter the number of slides loaded, and click on "Start Run".

END OF RUN INSTRUCTIONS

- All runs will go into a hold step before Counterstain/Slide Cleaning. To complete the run, press the logo button on the instrument. If Counterstain and/or Slide Cleaning were selected in the protocol, the instrument will perform these functions then stop. If Counterstain and/or Slide Cleaning were not selected, the instrument will "home," and then the run will end.
- When the run ends, open the instrument and collect each slide in a slide holder previously filled with Reaction Buffer. Rinse off the slides by immersing them in a solution made of a few drops of dish soap and warm water. Rinse the slides thoroughly before dehydration of the tissue through a battery of increasing concentration of Alcohol and Xylene. Coverslip the slides and air-dry before use.

TROUBLESHOOTING

- If the positive control exhibits weaker staining than expected, other positive controls run during the same instrument run should be checked to determine if it is because of the primary antibody or one of the common secondary reagents.
- If the positive control is negative, it should be checked to ensure that the slide has the proper bar code label. If the slide is labeled properly, other positive controls run on the same instrument run should be checked to determine if it is because of the primary antibody or one of the common secondary reagents. Tissues may have been improperly collected, fixed, or deparaffinized. The proper procedure should be followed for collection, storage and fixation.
- If excessive background staining occurs, high levels of endogenous biotin may be present. Include a biotin blocking step in the staining protocol.
- If all of the paraffin has not been removed, there may be no staining. Repeat the deparaffinization procedure.
- If specific antibody staining is too intense, repeat the staining run and shorten the incubation time by 4 minute intervals until the desired stain intensity is achieved.
- If tissue sections wash off the slide, slides should be checked to ensure that they are positively charged.
- For corrective action, refer to the Instructions for Use section, the instrument User Guide or contact your local support representative.
- If a reagent dispenser does not dispense fluid, check the priming chamber or meniscus for foreign materials or particulates, such as fibers or precipitates. If the dispenser is blocked, do not use the dispenser and contact your local support representative. Otherwise, re-prime the dispenser by aiming the dispenser over a waste container, removing the nozzle cap, and pressing down on the top of the dispenser.

REFERENCES

- Occupational Safety and Health Standards: Occupational exposure to hazardous chemicals in laboratories. (29 CFR Part 1910.1450). Fed. Register.
- Directive 2000/54/EC of the European Parliament and Council of 24 June 2020 on the protection of workers from risks related to exposure to biological agents at work.

Symbols

Ventana uses the following symbol in addition to those listed in the ISO 15223-1 standard (for USA: see elabdoc.roche.com/symbols for more information).

Global Trade Item Number

REVISION HISTORY

Rev	Updates
G	Updates to Warnings and Precautions section. Removed Protocols section and NexES information. Updated to current template.

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